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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Display Date 10-28-02
Publication Date 10-29-02
Certifier D. Hawkins

Food and Drug Administration

[Docket No. 02N–0461]

Antimicrobial Drug Development; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

The Food and Drug Administration (FDA) is announcing a public workshop, cosponsored with the Infectious Diseases Society of America (IDSA) and the Pharmaceutical Research and Manufacturers of America (PhRMA), regarding antimicrobial drug development. The public workshop is intended to provide information for and gain perspective from advocacy groups, interested health care providers, academia, and industry organizations on various aspects of antimicrobial drug development, including the selection of delta in noninferiority (equivalence) clinical trials, the need for newer antimicrobial agents for the treatment of resistant pathogens, and clinical trial design. The input from this public workshop will help in developing topics for further exploration.

Date and Time: The public workshop will be held on November 19 and 20, 2002, from 9 a.m. to 5 p.m.

Location: The public workshop will be held in the Center for Drug Evaluation and Research Advisory Committee Conference Room, rm. 1066, 5630 Fishers Lane, Rockville, MD. Seating is limited and available only on a first-come, first-served basis. Please note there is very limited parking in the

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vicinity of 5630 Fishers Lane, but it is near the Twinbrook Metro station. Please bring picture identification in order to clear building security.

Contact Person: John H. Powers, Center for Drug Evaluation and Research (HFD–104), Food and Drug Administration, 9201 Corporate Blvd., Rockville, MD 20850, 301–827–2350, e-mail: powersjoh@cder.fda.gov, or Leo Chan, Center for Drug Evaluation and Research (HFD–104), Food and Drug Administration, 9201 Corporate Blvd., Rockville, MD 20850, 301–827–2350, e-mail: chanl@cder.fda.gov.

Registration: Preregistration is required. Send registration information (including name, title, firm name, address, telephone, and fax number) to Leo Chan (see the *Contact Person* section of this document) by November 12, 2002. There is no registration fee for the public workshop. Space is limited; therefore, interested parties are encouraged to register early.

Persons needing a sign language interpreter or other special accommodations should notify the contact person at least 7 days in advance.

SUPPLEMENTARY INFORMATION: FDA is announcing a public workshop, cosponsored with IDSA and PhRMA, regarding antimicrobial drug development. On February 19 and 20, 2002, a public meeting of FDA's Anti-Infective Drugs Advisory Committee was held to discuss issues related to the selection of delta in noninferiority (equivalence) clinical trials and the development of antimicrobial agents for the treatment of resistant pathogens (67 FR 3726, January 25, 2002). This public workshop will further expand the discussion of both issues as well as focus on general considerations in designing clinical trials for antimicrobial products. Additional discussion topics include drug development for acute bacterial meningitis, acute exacerbation of chronic bronchitis, and hospital-acquired pneumonia. The

input from this public workshop will help in developing topics for further exploration.

The agency encourages individuals, patient advocates, industry, consumer groups, health care professionals, researchers, and other interested persons to attend this public workshop.

Transcripts: Transcripts of the public workshop will be available for review at the Dockets Management Branch Public Reading Room, Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852 and on the Internet at http://www.fda.gov/ohrms/dockets/dockets/dockets.htm or you may request a transcript of the public workshop from the Freedom of

Information Staff (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A–16, Rockville, MD 20857, approximately 20 working days after the public workshop, at a cost of 10 cents per page.

Dated: 10-23-02
October 23, 2002.

Margaret M. Dotzel,
Associate Commissioner for Policy.

[FR Doc. 02–????? Filed ??–??–02; 8:45 am]

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